

510(k) SUMMARY

K 100558

**Title:** Quanta System QUANTA Diode Laser Family

**Submitter:** Quanta System SpA  
via IV Novembre,116  
21058 Solbiate  
Olona VA / Italy

**Contact:** Dr. Isabella Carrer  
Medical Division Manager

**Date Prepared:** October 29, 2009

**Device Trade Name:** Quanta System QUANTA Diode Laser Family

**Common Name:** Laser surgical instrument for use in general surgery and dermatology

**Classification Name:** Instrument, surgical, powered, laser

**Predicate Devices:**

- Quanta System Diode Medical Laser Family (K072034);
- Quanta System Polysurge Diode Laser Family (K083613)
- Lightmed LightLas 532 (K091534)
- Quantel IDAS (K053604)
- Biolitec Ceralas Multiwavelength 980/1470nm Diode Laser System (K090164)

**Intended Use / Indications for Use:** The Quanta System QUANTA Diode Laser Family, including the QUANTA532, QUANTA808, QUANTA940, QUANTA980, QUANTA1064, QUANTA1320, QUANTA1470, and QUANTA1950 (and all their double wavelength combination and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery(PLDD), Gastroenterology, Head/neck/ENT and Radiology,

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Endovascular coagulation, Oral Surgery and Dental procedures. The **QUANTA980** and **QUANTA1470 Diode Laser** are further indicated for laser assisted lipolysis.

**LASER 808nm and 980nm**

**Urology:**

- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporization of the prostate

**General Surgery:**

- Rectal and anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparoscopic)
- Bowel resection (open and laparoscopic)
- Colectomy
- Liver resection
- Resection of organs
- Thyroidectomy
- Adhesiolysis
- Hepatobiliary tumors
- Thoracotomy
- Cholecystectomy (open and laparoscopic)
- Condyloma
- Breast biopsy

**Neurosurgery:**

- Percutaneous Disc Decompression (PLDD)
- Discectomy
- Hemostasis in conjunction with meningiomas

**Gynecology:**

- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

**Ophthalmology:**

- Dacryocystorhinostomy  
transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

**Orthopedics:**

- Dissect and coagulate

**Gastroenterology:**

- Hemostasis of colonoscopy
- Hemostasis of esophageal varices
- Excision of polyps

**Arthroscopy:**

- Chondromalacia
- Synovectomy
- Menisectomy

**Thoracic Surgery:**

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

**Pulmonology:**

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign an malignant pulmonary  
obstruction

**Otolaryngology ENT:**

- Removal of benign lesions from the ear,  
nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in  
situ
- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules,  
polyps and cyst

**Dental Application:**

- Frenectomy

- Frenotomy
- Biopsy
- Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

**Pulmonary Surgery:**

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

**Cardiac Surgery:**

- Coagulation and hemostasis of cardiac tissue

**Dermatology/Aesthetics:**

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminate, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridment.
- Seborrhic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

**Plastic Surgery:**

- Cut, coagulation & vaporization
- Resurfacing non
- Blepharoplasty

**Vascular Surgery:**

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

**LASER 940nm:**

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology.

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficialvein reflux.

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85 cc.

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including

marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications: Excisional and incisional biopsies Exposure of unerupted teeth; Fibroma removal; Frenectomy; Frenotomy; Gingival troughing for crown impressions; Gingivectomy; Gingivoplasty; Gingival incision and excision; Haemostasis and coagulation; Implant recovery; Incision and drainage of abscess; Leukoplakia; Operculectomy; Oral papillectomies; Pulpotomy; Pulpotomy as an adjunct to root canal therapy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; Vestibuloplasty

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

#### **LASER 980nm:**

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein. The QUANTA980 Diode Laser is further indicated for laser assisted lipolysis.

The device is specifically indicated for use as follows:

#### **Ear, Nose and Throat and Oral Surgery (Otolaryngology)**

Hemostasis, incision, excision, ablation, coagulation, and vaporization of

tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

### **Arthroscopy**

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint

tissues during arthroscopic surgery. Examples include:

- Menisectomy
- Synovectomy
- Chondromalacia

### **Gastroenterology**

Hemostasis, incision, excision, ablation, coagulation and vaporization of

tissue in the upper and lower gastrointestinal tracts and also with

endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

### **General Surgery, Dermatology, Plastic Surgery and Podiatry**

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.

<b>Quanta System S.p.a.</b> Via IV Novembre 116, SOLBIATE OLONA (VA)	510(K) PREMARKET NOTIFICATION		FDA F D 0.02.C
	<b>Product</b> QUANTA DIODE LASER FAMILY	<b>Revision</b> 13/03/2010	<b>Page 51 of 167</b>

Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

### **Urology**

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction



- Excision and vaporization of condyloma
- Lesions of external genitalia
- Vaporization of the prostate to treat benign prostatic hyperplasia (BPH)

### **Gynecology**

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

### **Neurosurgery**

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include: hemostasis in conjunction with meningiomas

### **Cardiac Surgery**

Hemostasis and coagulation of soft tissue, including cardiac tissue.

### **Pulmonary Surgery**

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

### **Dental Applications**

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy,

implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

### **Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux**

Indicated for use in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

### **LASER 1064nm**

### **DERMATOLOGY/ PLASTIC SURGERY**

Photocoagulation:

- Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful)

### **DISCECTOMY**

Percutaneous Lumbar Discectomy

### **GASTROINTESTINAL**

Tissue Ablation:

- Benign and Malignant Neoplasm
- Polyps
- Colitis
- Ulcers
- Aniodysplasia
- Hemorrhoids

**Hemostasis:**

- Varices
- Esophangitis
- Esophageal Ulcer
- Mallory-Weiss Tear
- Gastric Ulcers
- Duodenal Ulcers
- Non-bleeding Ulcers
- Gastric Erosions

**GENERAL SURGERY**

**Soft Tissue:**

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation

**Vessel Coagulation**

**GENITOURINARY SURGERY**

**Ablation and Hemostasis:**

- Superficial Urinary Bladder Tumors
- Invasive Bladder Carcinoma
- Urethral Strictures
- Lesions of the External Genitalia

**GYNECOLOGICAL TISSUE ABLATION**

- Endometrial Ablation (menorrhagia)
- Soft Tissue Excisional Conization
- Submucous Fibroids
- Polyps
- Septa

**NEUROSURGERY**

**Hemostasis**

## **ORTHOPEDIC SURGERY**

Soft Tissue (incision and excision):

- Knee
- Shoulder

## **OTORHINOLARYNGOLOGY SURGERY**

Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation
- Vessel Coagulation

## **PROSTATECTOMY**

Soft Tissue Coagulation:

- Benign Prostatic Hyperplasia (BPH Prostatectomy)

## **PULMONARY SURGERY**

Palliative Treatment:

- Benign and Malignant Pulmonary Airway Obstructions

## **LASER 1320 nm**

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles. For treatment of back acne and atrophic acne scars. For treatment of reflux of the great and small saphenous veins associated with varicose veins and varicosities.

**LASER 1470nm:**

The QUANTA Diode Laser System is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures including via endoscopes. The QUANTA Diode Laser System is generally indicated for use in endovenous occlusion of the greater saphenous vein. The QUANTA1470 Diode Laser is further indicated for laser assisted lipolysis.

The device is specifically indicated for use as follows:

**Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux**

Indicated for use in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

**LASER 1950nm:****Urology**

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral strictures
- Bladder neck incisions
- Ablation and resection of bladder tumors, urethral tumors and ureteral tumors
- Ablation of Benign Prostatic hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)
- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of the external genitalia

**Gastroenterology**

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation

and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Rendu disease
- Vascular malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric erosions

### **Thoracic/Pulmonary Surgery**

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Laryngeal lesions
- Airway obstruction including carcinoma
- Polyps and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree

### **Gynecology**

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Intra-uterine treatment of submucous

- fibroids, benign
- endometrial polyps and uterine septum by incision, excision,
- ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of
- the cervix
- 

### **Ear, Nose and Throat (Otolaryngology)**

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal/sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and
- laryngeal
- Tonsillectomy
- Adenoidectomy

### **Dermatology/Plastic Surgery**

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue in therapeutic plastic, dermatologic and aesthetic procedures including:

- Basal Cell carcinomas
- Lesions of the skin and subcutaneous tissue
- Skin tags
- Plantar warts

### **Arthroscopy**

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

Ablation of soft and cartilaginous tissue in minimally invasive spinal surgery including:

- Percutaneous laser disc  
decompression/discectomy (PLDD)
- Foraminoplasty
- Ablation and coagulation of soft  
vascular and non vascular tissue

### **General Surgery**

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal  
organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of decubitus ulcers
- Hemorrhoids
- Debridement of statis ulcers
- Biopsy

### **LASER 532nm:**

#### **Ophthalmology:**

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation
- Macular Treatments



- Laser Trabeculoplasty

**Otolaryngology:**

- Stapedectomy
- Stapedotomy
- Myringotomy
- Lysis of adhesions
- Control of bleeding
- Removal of acoustic neuromas
- Soft tissue adhesion in micro/macro otologic procedures.

**Dermatology:**

**Technological  
Characteristics:**

- Vascular lesion
- Pigmented lesion

The QUANTA Diode Laser System includes 36 models (8 single wavelength and 28 double wavelength) :

<b>Models</b>	<b>Wavelength</b>	<b>Laser Power</b>
<b>QUANTA532</b>	532nm	8W
<b>QUANTA808</b>	808nm	30W
<b>QUANTA940</b>	940nm	30W
<b>QUANTA980</b>	980nm	30W
<b>QUANTA1064</b>	1064nm	30W
<b>QUANTA1320</b>	1320nm	10W
<b>QUANTA1470</b>	1470nm	15W
<b>QUANTA1950</b>	1950nm	5W

- Model **QUANTA 532** is indicated for **Ophthalmology, Otolaryngology and Dermatology**
- Model **QUANTA808** is indicated for Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy (PLDD), Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery, Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures.

- Model **QUANTA940** is indicated for Urology (BPH), Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology, Endovascular Surgery and Dental Procedures.
- Model **QUANTA980** is indicated for use in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology (BPH), gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein. It is also indicated for Laser Assisted Lipolysis
- Model **QUANTA1064** is indicated for use in Dermatology/ Plastic Surgery, Discectomy, Gastrointestinal Surgery, General Surgery, Genitourinary Surgery, Gynecological Tissue Ablation, Neurosurgery, Orthopedic Surgery, Otorhinolaryngology Surgery, Prostatectomy, Pulmonary Surgery.
- Model **QUANTA1320** is indicated for use in Dermatology and endovascular surgery.
- Model **QUANTA1470** is indicated for use in endovascular surgery and for laser assisted lipolysis.
- Model **QUANTA1950** is indicated for use in Urology, Gastroenterology, Thoracic/Pulmonary Surgery, Gynecology, Ear, Nose and Throat (Otolaryngology), Dermatology/Plastic Surgery, Arthroscopy, General Surgery

The QUANTA Diode Laser Family is designed with 4 major subsystems: (1) an external structure; (2) power electronics; (3) display with control electronics, which controls the power electronics, the user interface and the laser source temperature via a thermostat board; and (4) the laser system with an opto-mechanical block composed of the laser source, the Peltier cooling system with dissipater and fans, the fiber launching system, the red diode aiming beam, and the power calibration

system. The fiber is connected to the system through an SMA 905 socket on the front panel. In addition to the four subsystems, the QUANTA Diode Laser Family incorporates several safety features, including a remote interlock, an emergency red push button and a key switch.

The external accessories include separate optical fibers and hand pieces for dental, dermatological and surgical applications, or for endovascular applications and laser assisted lipolysis.

**NOTE: In all double wavelength models it's possible to use only one at a time. It's not possible to use them simultaneously or sequentially. In double models the different wavelengths are delivered through two different optical fibers and hanpieces. The software allows the operator to choose and use a single wavelength at a time. To switch from one wavelength to another the laser device must be always switched off and switched on. In this way it's impossible to use two wavelengths simultaneously or sequentially.**

**Performance Data**      None

**Substantial  
Equivalence:**

The Quanta System QUANTA Diode Laser Family is as safe and effective as the predicate devices. The QUANTA Diode Laser Family has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the QUANTA Diode Laser Family and its predicate devices raise no new issues of safety or effectiveness. Thus, the QUANTA Diode Laser Family is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

JUL 22 2010

Quanta System, S.P.A.  
% Regulatory Technology Services, LLC  
Mr. Mark Job  
1394 25<sup>th</sup> Street, NW  
Buffalo, Minnesota 55313

Re: K100558  
Trade/Device Name: QUANTA Diode Laser Family  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: Class II  
Product Code: GEX  
Dated: July 20, 2010  
Received: July 21, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
And Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

<b>Quanta System S.p.a.</b>  Via IV Novembre 116, SOLBIATE OLONA (VA)	<b>INDICATIONS FOR USE STATEMENT</b>  <div> <div>Product</div> <div>QUANTA DIODE LASER FAMILY</div> </div> <div> <div>Revision</div> <div>07/06/2010</div> </div>	<b>FDA F D 14.01.A</b>  Page 1 of 14
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## Indications for Use Statement

510(k) Number (if known): \_\_\_\_\_

Device Name: **QUANTA Diode Laser Family**

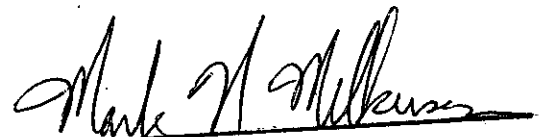
### Indications for Use:

The Quanta System QUANTA Diode Laser Family, including the QUANTA532, QUANTA808, QUANTA940, QUANTA980, QUANTA1064, QUANTA1320, QUANTA1470, and QUANTA1950 (and all their double wavelength combination and their delivery accessories used to deliver optical energy) are indicated for use in surgical applications requiring the vaporization, incision, excision, ablation, cutting and hemostasis, or coagulation of soft tissue in conjunction with endoscopic equipment for medical specialist including: Urology (BPH), Genitourinary (Urology), Thoracic Surgery, Plastic Surgery and Dermatology, Aesthetics including vascular lesions and hair removal, General Surgery, Ophthalmology, Orthopedics, Podiatry, Arthroscopy, Spinal Surgery, Gynecology, Pulmonary Surgery, Neurosurgery(PLDD), Gastroenterology, Head/neck/ENT and Radiology, Endovascular coagulation, Oral Surgery and Dental procedures. **The QUANTA980 and QUANTA1470 Diode Laser are further indicated for laser assisted lipolysis.**

### LASER 808nm and 980nm

#### Urology:

- Lesions of external genitalia
- Circumcision
- Condyloma
- Bladder tumors
- Bladder neck incisions
- Vaporization of the prostate

  
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#### General Surgery:

- Rectal and anal hemorrhoidectomy
- Mastectomy
- Dermabrasion
- Appendectomy (open and laparoscopic)
- Bowel resection (open and laparoscopic)
- Colectomy
- Liver resection
- Resection of organs
- Thyroidectomy
- Adhesiolysis
- Hepatobiliary tumors
- Thoracotomy
- Cholecystectomy (open and laparoscopic)
- Condyloma
- Breast biopsy

Written by: MED

Checked by:

Approved by:

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**Neurosurgery:**

- Percutaneous Disc Decompression (PLDD)
- Discectomy
- Hemostasis in conjunction with meningiomas

**Gynecology:**

- Cervical conization
- Myomectomy
- Endometrial ablation
- Ovarian cystectomy
- Appendectomy

**Ophthalmology:**

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor excision
- Blepharoplasty

**Orthopedics:**

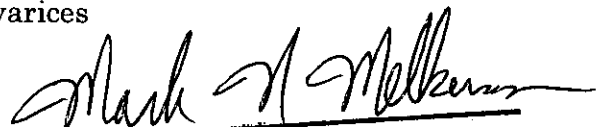
- Dissect and coagulate

**Gastroenterology:**

- Hemostasis of colonoscopy
- Hemostasis of esophageal varices
- Excision of polyps

**Arthroscopy:**

- Chondromalacia
- Synovectomy
- Meniscectomy



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**Thoracic Surgery:**

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

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**Pulmonology:**

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary obstruction

**Otolaryngology ENT:**

- Removal of benign lesions from the ear, nose and throat
- Excision of carcinoma of the larynx
- Incision and excision of carcinoma in situ

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- Neck dissection
- Laryngeal papillomectomy
- Removal of vocal cord/fold nodules, polyps and cyst

#### Dental Application:

- Frenectomy
- Frenotomy
- Biopsy
- Pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening

#### Pulmonary Surgery:

- Endoscopic pulmonary applications
- Tracheal bronchial lesions
- Benign and malignant pulmonary or stricture

#### Cardiac Surgery:

- Coagulation and hemostasis of cardiac tissue

#### Dermatology/Aesthetics:

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinullectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, Rosacea, Angioma, venous lakes Couperosis, Cherry angioma, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines. Epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminata, warts, small non malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcom. Warty leucoplasty and ulcers debridement.
- Seborrhic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment
- Hair removal of unwanted hair from skin type I-V

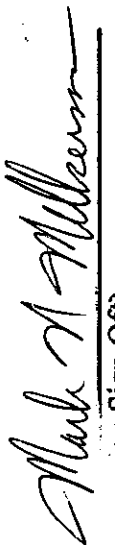
#### Plastic Surgery:

- Cut, coagulation & vaporization
- Resurfacing non
- Blepharoplasty

#### Vascular Surgery:

- Endoluminal or endovenous laser surgery for saphenous incompetent veins

#### LASER 940nm:

  
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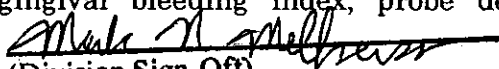
The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in medicine and surgery, in the following medical specialties: Urology, Plastic Surgery, General Surgery, Dermatology, Gynecology, Pulmonary Surgery, Gastroenterology, ENT, Radiology.

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in cutting, vaporization, ablation and coagulation of soft tissue in conjunction with endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, gastroscopes, cystoscopes, and colonoscopies), in incision/excision, vaporization, ablation and coagulation of soft tissue in contact and non-contact open surgery (with or without a handpiece), in the treatment and/or removal of vascular lesions (tumors) and removal of unwanted hair, and for endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are intended for use in the treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men over the age of 50 with prostates with median and/or lateral lobes ranging in total volume from 28-85 cc.

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissue including marginal and inter-dental gingival and epithelial lining of free gingival and the following specific indications: Excisional and incisional biopsies Exposure of unerupted teeth; Fibroma removal; Frenectomy; Frenotomy; Gingival troughing for crown impressions; Gingivectomy; Gingivoplasty; Gingival incision and excision; Haemostasis and coagulation; Implant recovery; Incision and drainage of abscess; Leukoplakia; Operculectomy; Oral papillectomies; Pulpotomy; Pulpotomy as an adjunct to root canal therapy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; Vestibuloplasty

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for Laser Periodontal procedures, including: Laser soft tissue curettage; Laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket; Sulcular debridement (removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility.)

  
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### **LASER 980nm:**

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein. The QUANTA980 Diode Laser is further indicated for laser assisted lipolysis.

The device is specifically indicated for use as follows:

#### **Ear, Nose and Throat and Oral Surgery (Otolaryngology)**

Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity. Examples include:

- Removal of benign lesions from the ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in situ
- Ablation and vaporization of hyperkeratosis
- Excision of carcinoma of the larynx
- Laryngeal papillomectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

#### **Arthroscopy**

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:

- Meniscectomy
- Synovectomy
- Chondromalacia

#### **Gastroenterology**

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures. Examples include:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps

#### **General Surgery, Dermatology, Plastic Surgery and Podiatry**

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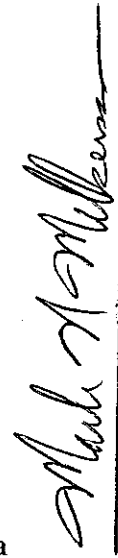
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Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.

Examples include:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of keloids
- Liver resection
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcers
- Hepatobiliary tumors
- Mastectomy
- Dermabrasion
- Vaporization and hemostasis of capillary hemangioma
- Excision, vaporization and hemostasis of abdominal tumors
- Excision, vaporization and hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorraphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs
- Debridement of wounds
- Photocoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.
- Treatment of reticular veins and branch varicosities

  
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## Urology

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues. Examples include:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Vaporization of the prostate to treat benign prostatic hyperplasia (BPH)

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## Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

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## Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Examples include: hemostasis in conjunction with meningiomas

## Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue.

## Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system. Examples include:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction
- Endoscopic pulmonary applications

## Dental Applications

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

## Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

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## **LASER 1064nm**

### **DERMATOLOGY/ PLASTIC SURGERY**

#### Photocoagulation:

- Colored Vascular Lesions of Skin (only if Argon Laser is unsuccessful)


### **DISCECTOMY**

#### Percutaneous Lumbar Discectomy

### **GASTROINTESTINAL**

#### Tissue Ablation:

- Benign and Malignant Neoplasm
- Polyps
- Colitis
- Ulcers
- Aniodysplasia
- Hemorrhoids



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#### Hemostasis:

- Varices
- Esophangitis
- Esophageal Ulcer
- Mallory-Weiss Tear
- Gastric Ulcers
- Duodenal Ulcers
- Non-bleeding Ulcers
- Gastric Erosions

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### **GENERAL SURGERY**

#### Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation

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Vessel Coagulation

## GENITOURINARY SURGERY

Ablation and Hemostasis:

- Superficial Urinary Bladder Tumors
- Invasive Bladder Carcinoma
- Urethral Strictures
- Lesions of the External Genitalia

## GYNECOLOGICAL TISSUE ABLATION

- Endometrial Ablation (menorrhagia)
- Soft Tissue Excisional Conization
- Submucous Fibroids
- Polyps
- Septa

## NEUROSURGERY

Hemostasis

## ORTHOPEDIC SURGERY

Soft Tissue (incision and excision):

- Knee
- Shoulder

## OTORHINOLARYNGOLOGY SURGERY


Soft Tissue:

- Skin Incision
- Tissue Dissection
- Excision (external tumors and lesions)
- Resection of Internal Organs (complete or partial)
- Tumors and Lesions
- Tissue Ablation
- Vessel Coagulation

## PROSTATECTOMY

Soft Tissue Coagulation:

- Benign Prostatic Hyperplasia (BPH Prostatectomy)

  
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## PULMONARY SURGERY

Palliative Treatment:

- Benign and Malignant Pulmonary Airway Obstruction

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### LASER 1320 nm

The Quanta System QUANTA Diode Laser Family (and their delivery accessories used to deliver optical energy) are indicated for use in dermatology for incision, excision, ablation and vaporization with hemostasis of soft tissue. For use in the treatment of fine lines and wrinkles. For treatment of back acne and atrophic acne scars. For treatment of reflux of the great and small saphenous veins associated with varicose veins and varicosities.

### LASER 1470nm:

The QUANTA Diode Laser System is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures including via endoscopes. The QUANTA Diode Laser System is generally indicated for use in endovenous occlusion of the greater saphenous vein. The QUANTA1470 Diode Laser System is further indicated for laser assisted lipolysis.

The device is specifically indicated for use as follows:

### **Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux**

Indicated for use in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

### LASER 1950nm:

#### **Urology**

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Urethral strictures
- Bladder neck incisions
- Ablation and resection of bladder tumors, urethral tumors and ureteral tumors
- Ablation of Benign Prostatic hypertrophy (BPH)
- Transurethral incision of the prostate (TUIP)

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- Laser Resection of the Prostate (HoLRP)
- Laser Enucleation of the Prostate (HoLEP)
- Laser Ablation of the Prostate (HoLAP)
- Condylomas
- Lesions of the external genitalia

### Gastroenterology

Open and endoscopic gastroenterology surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Appendectomy
- Polyps
- Biopsy
- Gall Bladder calculi
- Biliary/bile duct calculi
- Ulcers
- Gastric ulcers
- Duodenal ulcers
- Non-bleeding ulcers
- Pancreatitis
- Hemorrhoids
- Cholecystectomy
- Benign and malignant neoplasm
- Angiodysplasia
- Colorectal cancer
- Telangiectasias
- Telangiectasias of the Osler-Weber-Renu disease
- Vascular malformation
- Gastritis
- Esophagitis
- Esophageal ulcers
- Varices
- Colitis
- Mallory-Weiss tear
- Gastric erosions



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### Thoracic/Pulmonary Surgery

Open and endoscopic thoracic and pulmonary surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including

- Laryngeal lesions
- Airway obstruction including carcinoma
- Polyps and granulomas
- Palliation of obstructing carcinomas of the tracheobronchial tree



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## Gynecology

Open and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including


- Intra-uterine treatment of submucous fibroids, benign
- endometrial polyps and uterine septum by incision, excision,
- ablation and or vessel coagulation
- Soft tissue excision procedures such as excisional conization of
- the cervix

## Ear, Nose and Throat (Otolaryngology)

Endoscopic endonasal surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Endonasal/sinus surgery
- Partial turbinectomy
- Polypectomy
- Dacryocystorhinostomy
- Frontal sinusotomy
- Ethmoidectomy
- Maxillary antrostomy
- Functional endoscopic sinus surgery
- Lesions or tumors of the oral, nasal, glossal, pharyngeal and
- laryngeal
- Tonsillectomy
- Adenoidectomy

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## Dermatology/Plastic Surgery

Incision, excision, resection, ablation, vaporization, coagulation and hemostasis of soft, mucosal, fatty and cartilaginous tissue in therapeutic plastic, dermatologic and aesthetic procedures including:

- Basal Cell carcinomas
- Lesions of the skin and subcutaneous tissue
- Skin tags
- Plantar warts

## Arthroscopy

Arthroscopy/Orthopedic surgery (excision, ablation and coagulation of soft and cartilaginous tissue)

Ablation of soft and cartilaginous tissue in minimally invasive spinal surgery including:

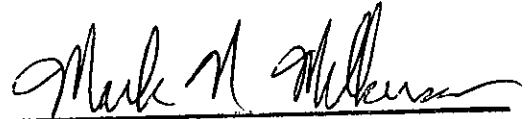
- Percutaneous laser disc decompression/discectomy (PLDD)
- Foraminoplasty
- Ablation and coagulation of soft vascular and non vascular tissue

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	<b>Product</b> <b>QUANTA DIODE</b> <b>LASER FAMILY</b>	<b>Revision</b> 07/06/2010	<b>Page 13 of 14</b>

## General Surgery

Open laparoscopic and endoscopic surgery (incision, excision, resection, ablation, vaporization, coagulation and hemostasis) including:

- Cholecystectomy
- Lysis of adhesions
- Appendectomy
- Biopsy
- Skin incision
- Tissue dissection
- Excision of external tumors and lesions
- Complete or partial resection of internal organs, tumors and lesions
- Mastectomy
- Hepatectomy
- Pancreatectomy
- Splenectomy
- Thyroidectomy
- Parathyroidectomy
- Herniorrhaphy
- Tonsillectomy
- Lymphadenectomy
- Partial nephrectomy
- Pilonidal Cystectomy
- Resection of lipoma
- Debridement of decubitus ulcers
- Hemorrhoids
- Debridement of statis ulcers
- Biopsy



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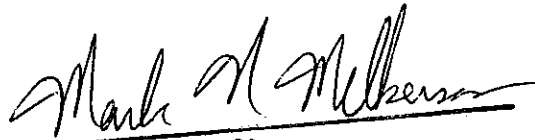
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**LASER 532nm:**

**Ophthalmology:**

- Retinal Photocoagulation
- Pan Retinal Photocoagulation
- Endophotocoagulation
- Macular Treatments
- Laser Trabeculoplasty

  
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**Otolaryngology:**

- Stapedectomy
- Stapedotomy
- Myringotomy
- Lysis of adhesions
- Control of bleeding
- Removal of acoustic neuromas
- Soft tissue adhesion in micro/macro otologic procedures.

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**Dermatology:**

- Vascular lesion
- Pigmented lesion

Prescription Use   X    
(Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use         
(21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Written by: MED

Checked by:

Approved by: